The purpose of this study is to determine the efficacy and safety of pembrolizumab given concomitantly with chemoradiation (CRT) and as maintenance therapy versus placebo plus CRT in participants with locally advanced head and neck squamous cell carcinoma (LA HNSCC). The primary hypothesis is that pembrolizumab in combination with CRT is superior to placebo in
Ein-/Ausschlusskriterien

**Inclusion Criteria:**

- Has a pathologically proven new diagnosis of oropharyngeal p16 positive, oropharyngeal p16 negative, or larynx/hypopharynx/oral cavity (independent of p16) squamous cell carcinoma. Participants with oral cavity tumors need to have unresectable disease. Participants with multiple synchronous tumors are not eligible for the study.

- Has provided tissue for Programmed Cell Death Receptor Ligand 1 (PD-L1) biomarker analysis from a core or excisional biopsy. If an excisional or incisional biopsy has been performed, participants remain eligible for the study provided the residual disease meets the staging criteria required for the trial (e.g., excisional biopsy of a lymph node with residual T4 primary). Prior surgical debulking, including tonsillectomy, for the head and neck cancer under study is not allowed.

- Has evaluable tumor burden (measurable and/or non-measurable tumor lesions) assessed by computed tomography scan or magnetic resonance imaging, based on RECIST version 1.1

- Is eligible for definitive CRT and not considered for primary surgery based on investigator decision

- Has Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 performed within 10 days prior to receiving the first dose of study therapy

- Female participants of childbearing potential must have a negative urine or serum pregnancy test within 72 hours prior to receiving the first dose of study therapy

- Female and male participants of reproductive potential must agree to use adequate contraception throughout the study period and for up to 180 days after the last dose of study therapy

**Exclusion Criteria:**

- Is currently participating or has participated in a study with an investigational agent or using an investigational device within 4 weeks of the first dose of study therapy

- Has received prior therapy with an anti-Programmed Cell Death Receptor 1 (PD-1), anti-PD-L1, anti-Programmed Cell Death Receptor Ligand 2 (PD-L2) agent or with an agent directed to another co-inhibitory T-cell receptor or has previously participated in clinical studies with pembrolizumab

- Has received a live vaccine within 30 days prior to the first dose of study therapy

- Has cancer outside of the oropharynx, larynx, and hypopharynx or oral cavity, such as
nasopharyngeal, sinus, other para-nasal, or other unknown primary head and neck cancer

- Has had prior systemic therapy, targeted therapy, radiotherapy treatment or radical surgery for head and neck cancer under study
- Has not recovered from major surgery prior to starting study therapy
- Has known active Hepatitis B or C
- Has known history of Human Immunodeficiency Virus (HIV)
- Has a diagnosis of immunodeficiency or is receiving systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior to the first dose of study therapy
- Has a history of (non-infectious) pneumonitis that required steroids or current pneumonitis
- Has an active autoimmune disease that has required systemic treatment in the past 2 years. Replacement therapy is not considered a form of systemic treatment.
- Has history of a diagnosed and/or treated hematologic or primary solid tumor malignancy, unless in remission for at least 5 years prior to randomization
- Has known active central nervous system (CNS) metastases and/or carcinomatous meningitis
- Has had previous allogeneic tissue/solid organ transplant
- Has active infection requiring systemic therapy
- Has a history of severe hypersensitivity reaction to pembrolizumab, Cisplatin or radiotherapy or their analogs
- Is pregnant or breast feeding or expecting to conceive or father children throughout the study period and for up to 180 days after the last dose of study therapy

**Studien-Rationale**

**Primary outcome:**

1. Event-free Survival (EFS) (Time Frame - Up to 5 years):

   EFS is the time from the date of randomization to the date of first record of disease progression per Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST 1.1) by Blinded Independent Central Review (BICR) or death.

**Secondary outcome:**

1. Overall Survival (OS) (Time Frame - Up to 5 years):

   OS is the time from randomization to death due to any cause.

2. Adverse Events (AEs) (Time Frame - From time of first dose of study treatment until the end of
follow-up (up to 5 years)):
Number of participants experiencing any sign, symptom, disease, or worsening of preexisting condition temporally associated with study therapy and irrespective of causality to study therapy

3. Treatment Discontinuations Due to AEs (Time Frame - From time of first dose of study treatment until the end of treatment (up to 1 year)):
Number of participants discontinuing study drug due to an AE

4. Global Health Status/Quality of Life (GHS/QoL) (Time Frame - Prior to the first dose of study treatment (Baseline) and at the time of last follow-up (up to 5 years)):
Change from baseline in GHS/QoL using the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Core Questionnaire (EORTC QLQ-C30)

5. Swallowing, Speech, and Pain Symptoms (Time Frame - Prior to the first dose of study treatment (Baseline) and at the time of last follow-up (up to 5 years)):
Change from baseline in swallowing, speech, and pain symptoms using the EORTC Head and Neck Questionnaire (EORTC QLQ-H&N35)

Studien-Arme

- **Experimental: Pembrolizumab + Cisplatin + CRT**
  
  **Participants receive a priming dose of pembrolizumab before initiation of CRT (either accelerated or standard fractionation radiotherapy regimen). During CRT, participants receive 2 doses of pembrolizumab and up to 3 cycles of Cisplatin (2 cycles during accelerated and 3 cycles during standard fractionation radiotherapy). Participants also receive up to an additional 14 cycles of pembrolizumab alone as maintenance therapy for a total of 17 cycles of pembrolizumab. If cisplatin and/or radiation therapy is discontinued, the participant may continue on treatment with pembrolizumab.**

- **Placebo Comparator: Placebo + Cisplatin + CRT**
  
  **Participants receive placebo before initiation of CRT (either accelerated or standard fractionation radiotherapy regimen). During CRT, participants receive 2 doses of placebo and up to 3 cycles of Cisplatin (2 cycles during accelerated and 3 cycles during standard fractionation radiotherapy). Participants also receive up to an additional 14 cycles of placebo alone for a total of 17 cycles of placebo. If cisplatin and/or radiation therapy is discontinued, the participant may continue on treatment with placebo.**

Geprüfte Regime

- **Pembrolizumab (KEYTRUDA®):**
  
  **Administered as an intravenous (IV) infusion every 3 weeks (Q3W)**

- **Placebo:**
  
  **Normal saline or dextrose solution administered as an IV infusion Q3W**

- **Cisplatin (Platinol® / Platinol®-AQ / ):**
  
  **100 mg/m^2 administered as an IV infusion Q3W**

- **Accelerated Fractionation (AFX) Radiotherapy:**
  
  **70 Gray (Gy) given in 35 fractions over 6 weeks**
- **Standard Fractionation (SFX) Radiotherapy:**
  70 Gy given in 35 fractions over 7 weeks

**Studienleiter**

**Medical Director**
Study Director
*Merck Sharp & Dohme Corp.*

**Studienlocations (3 von 151)**

**UCLA Medical Center (Site 0273)**
90095 Los Angeles
United States

**University of California San Francisco (Site 0274)**
94115 San Francisco
United States

**St. Joseph Heritage Healthcare (Site 0254)**
95403 Santa Rosa
United States

**Smilow Cancer Hospital at Yale New Haven (Site 0256)**
06510 New Haven
United States

**Rush University Medical Center (Site 0260)**
60612 Chicago
United States

**Indiana University (Site 0264)**
46202 Indianapolis
United States

**Mary Bird Perkins Cancer Center at St. Tammany Parish Hospital (Site 0281)**
70809 Baton Rouge
United States

**University of Massachusetts Memorial Medical Center (Site 0285)**
University of Michigan Hospital and Health Systems (Site 0267)
48109 Ann Arbor
United States

Barbara Ann Karmanos Cancer Institute (Site 0272)
48201 Detroit
United States

Mercy Clinic Cancer and Hematology - Chub O'Reilly Cancer Center (Site 0290)
65804 Springfield
United States

St. Vincent Healthcare Frontier Cancer Center (Site 0286)
59102 Billings
United States

Comprehensive Cancer Centers of Nevada (Site 8004)
89169 Las Vegas
United States

University of Rochester - James P. Wilmot Cancer Center (Site 0255)
14642 Rochester
United States

Oncology Hematology Care, Inc. (Site 8003)
45242 Cincinnati
United States

Willamette Valley Cancer Institute and Research Center (Site 8000)
97401 Eugene
United States

St. Luke's Cancer Center - Anderson (Site 0251)
18045 Easton
United States

St. Francis Hospital Cancer Center (Site 1461)
29607 Greenville
United States

**Texas Oncology-Arlington North (Site 8005)**
76014 Arlington
United States

**Texas Oncology-Austin Central (Site 8002)**
78731 Austin
United States

**Texas Oncology PA (Site 8001)**
75601 Longview
United States

**University of Virginia Health System (Site 0261)**
22908 Charlottesville
United States

**Seattle Cancer Care Alliance/Univ of Washington Medical Center (Site 0269)**
98109 Seattle
United States

**Medical Oncology Associates (Summit Cancer Centers) (Site 0257)**
99208 Spokane
United States

**Liverpool Hospital (Site 0301)**
2170 Liverpool
Australia

**Blacktown Hospital Western Sydney Local Health District (Site 0304)**
2148 Blacktown
Australia

**Princess Alexandra Hospital (Site 0305)**
4102 Brisbane
Australia

**Royal Brisbane and Women's Hospital (Site 0302)**
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4000 Liege
Belgium

Clinique et Maternite Sainte-Elisabeth (Site 0653)
5000 Namur
Belgium

Hospital Santa Izabel - Santa Casa de Misericordia da Bahia (Site 0006)
40050-410 Salvador
Brazil

Centro Regional Integrado de Oncologia (Site 0002)
60336-045 Fortaleza
Brazil

Liga Norte Riograndense Contra o Cancer (Site 0005)
59075-740 Natal
Brazil

Hospital Nossa Senhora da Conceicao (Site 0001)
91350-200 Porto Alegre
Brazil

Hospital de Clinicas de Porto Alegre (Site 0011)
90035-903 Porto Alegre
Brazil

Fundacao Pio XII - Hospital de Cancer de Barretos (Site 0003)
14784-400 Barretos
Brazil

Instituto do Cancer de Sao Paulo - ICESP (Site 0004)
01246-000 Sao Paulo
Brazil

Hospital das Clinicas da FMUSP de Ribeirao Preto (Site 0008)
14048-900 Ribeirao Preto
Brazil

Instituto Nacional do Cancer Jose Alencar Gomes da Silva INCA (Site 0010)
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Centro Medico Imbanaco de Cali S.A (Site 0156)
760042 Cali
Colombia

Centro de Investigacion Clinica del Country (Site 0155)
110221 Bogota
Colombia

FN Brno. (Site 0703)
625 00 Brno
Czechia

Fakultni Nemocnice Hradec Kralove (Site 0705)
500 05 Hradec Kralove
Czechia

Fakultni nemocnice Olomouc (Site 0701)
775 20 Olomouc
Czechia

Fakultni nemocnice Ostrava (Site 0702)
708 52 Ostrava
Czechia

Nemocnice Na Bulovce (Site 0700)
180 81 Praha 8
Czechia

2. LF UK a FN Motol (Site 0704)
150 06 Praha
Czechia

Centre Jean Bernard Laboratoire Mahe Meziani (Site 0760)
72000 Le Mans
France

Clinique Francois Chenieux (Site 0757)
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Azienda Ospedaliera San Paolo (Site 0952)
20142 Milano
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Istituto Nazionale Tumori IRCCS Fondazione Pascale (Site 0951)
80121 Napoli
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Chiba Cancer Center (Site 0358)
Hiroshima University Hospital (Site 0352)
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Osaka International Cancer Institute (Site 0355)
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The Cancer Institute Hospital of JFCR (Site 0357)
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Severance Hospital Yonsei University Health System (Site 0452)
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Samsung Medical Center (Site 0450)
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Noordwest Ziekenhuisgroep NWZ (Site 1350)
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1081 HV Amsterdam
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**UMCG (Site 1351)**
9713 GZ Groningen
Netherlands

**UMC St. Radboud (Site 1356)**
6525 GA Nijmegen
Netherlands

**Erasmus University Medical Center (Site 1354)**
3015 GD Rotterdam
Netherlands

**Capital & Coast District Health Board - Wellington Hospital (Site 0400)**
6021 Wellington
New Zealand

**Dolnoslaskie Centrum Onkologii. (Site 1001)**
53-413 Wroclaw
Poland

**Mazowiecki Szpital Onkologiczny (Site 1015)**
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**Beskidzkie Centrum Onkologii im. Jana Pawla II (Site 1005)**
43-300 Bielsko-Biala
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**Szpital Morski im. PCK. Szpitale Pomorskie Sp. Z o.o (Site 1007)**
81-519 Gdynia
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**Centrum Onkologii. Instytut im. Marii Sklodowskiej-Curie (Site 1010)**
44-101 Gliwice
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Szpital Specjalistyczny im. Ludwika Rydygiera w Krakowie (Site 1008)
31-826 Krakow
Poland

Zachodniopomorskie Centrum Onkologii (Site 1013)
71-730 Szczecin
Poland

Centrum Onkologii-Instytut im. Marii Skłodowskiej-Curie (Site 1000)
02-781 Warszawa
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H.U. Vall de Hebron (Site 1052)
08035 Barcelona
Spain

Hospital Duran i Reynals (Site 1053)
08907 Hospitalet de Llobregat
Spain

Hospital Doce de Octubre (Site 1054)
28024 Madrid
Spain

Hospital Universitario Ramon y Cajal (Site 1055)
28034 Madrid
Spain

Hospital Clinico San Carlos (Site 1051)
28040 Madrid
Spain

Hospital Universitario Virgen de la Victoria (Site 1056)
29010 Malaga
Spain

Hospital Gral Universitario de Valencia (Site 1050)
Chang Gung Medical Foundation - Kaohsiung (Site 0501)
83301 Kaohsiung
Taiwan

Taichung Veterans General Hospital (Site 0506)
407 Taichung
Taiwan

National Cheng Kung University Hospital (Site 0503)
70403 Tainan
Taiwan

National Taiwan University Hospital (Site 0500)
10048 Taipei
Taiwan

MacKay Memorial Hospital (Site 0505)
105 Taipei
Taiwan

Taipei Veterans General Hospital (Site 0504)
112 Taipei
Taiwan

Linkou Chang Gung Memorial Hospital (Site 0502)
333 Taoyuan
Taiwan

Basken Adana Dr. Turgut Noyan Uygulama ve Arastirma Merkezi (Site 1103)
01250 Adana
Turkey

Hacettepe Universitesi Tip Fakultesi Hastanesi (Site 1102)
06100 Ankara
Turkey

Ankara Sehir Hastanesi (Site 1108)
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Imperial Healthcare NHS Trust Charing Cross Hospital (Site 1204)
SW3 6JJ London
United Kingdom

Lancashire Teaching Hospitals NHS Foundation Trust (Site 1208)
W6 8RF London
United Kingdom

University Hospital Southampton NHS Foundation Trust (Site 1203)
PR2 9HT Preston
United Kingdom

Royal Marsden NHS Foundation Trust (Site 1201)
SM2 5PT Sutton
United Kingdom

Quelle: ClinicalTrials.gov